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Gregory H. Zayia – Reg. No. 48,059

Name of applicant, assignee or
Registered Representative

Gregory Zayia

Signature

March 23, 2005

Date of Signature

Our Case No. 4921/100

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Barnard Stewart Silver

Serial No. 09/618,813

Filing Date: July 18, 2000

For: Sweetening Compositions and Foodstuffs Comprised Thereof

Examiner Leslie A. Wong

Group Art Unit No. 1761

RESPONSE TO NOTIFICATION OF NON-COMPLIANCE WITH THE REQUIREMENTS OF 37 CFR 41.37(c)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Responsive to the Notification of Non-Compliance with the Requirements of 37 CFR 41.37(c) mailed December 23, 2004, Appellant submits herewith an Amended Appeal Brief wherein the section entitled "Summary of Claimed Subject Matter" has been revised in full compliance with the provisions of 37 CFR § 41.37(c)(1)(v).

Respectfully submitted,

Gregory Zayia

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Our Case No. 4921/100

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Barnard Stewart Silver

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For: Sweetening Compositions and Foodstuffs Comprised Thereof

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AMENDED APPEAL BRIEF SUBMITTED IN RESPONSE TO NOTIFICATION OF NON-COMPLIANCE WITH THE REQUIREMENTS OF 37 CFR 41.37(c)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

By the filing of this Appeal Brief in accordance with 37 CFR § 41.37, Appellant respectfully requests reconsideration by the Board of Patent Appeals and Interferences in the above-identified patent application.

Real Party in Interest

The real party in interest is Barnard Stewart Silver, an individual having a place of residence in Salt Lake City, Utah.

Related Appeals and Interferences

Currently, there are no pending appeals or interferences related to the present appeal.

Status of Claims

1. Claims 1-29 are present and active in the application.
2. Claims 1-29 have been twice rejected.
3. The rejections of claims 1-29 are being appealed.

Status of Amendments

No amendment has been filed subsequent to the Final Office Action dated October 7, 2003.

Summary of Claimed Subject Matter

There are seven (7) independent claims involved in this appeal: claims 1, 13, 20, 21, 22, 26, and 28.

1. Independent claim 1 recites a sweetening composition that includes (a) at least one sweetening agent comprising a polyol; and (b) inulin, which comprises at least about 25 percent by weight of the combination of the at least one sweetening agent and the inulin (e.g., specification, page 3, lines 5-10; page 5, lines 22-28; page 7, lines 3-7; page 11, lines 10-18; page 12, lines 2-10; page 13, lines 4-12; etc.).

2. Independent claim 13 recites a sweetening composition that includes (a) a sweetening agent comprising a polyol and fructose; and (b) inulin, which comprises at least about 25 percent by weight of the combination of the sweetening agent and the inulin (e.g., specification, page 3, lines 5-10; page 5, lines 22-28; page 7, lines 3-7; page 9, lines 5-20; page 12, lines 2-10; etc.).

3. Independent claim 20 recites a sweetening composition that includes (a) a sweetening agent comprising at least one polyol selected from the group consisting of xylitol, sorbitol, and a combination thereof; and (b) inulin, which comprises at least about 25 percent by weight of the combination of the at least one sweetening agent and the inulin (e.g., specification, page 3, lines 5-10; page 5, line 22 to page 6, line 5; page 7, lines 3-7; etc.).

4. Independent claim 21 recites a sweetening composition that includes (a) a sweetening agent comprising xylitol, lactose, and fructose; and (b) inulin, which comprises at least about 25 percent by weight of the combination of the sweetening agent and the inulin (e.g., specification, page 3, lines 5-10; page 5, lines 22-27; page 7, lines 3-7; page 9, line 5 to page 10, line 9; etc.).

5. Independent claim 22 recites a sweetening composition that includes (a) a sweetening agent comprising lactose and xylitol; and (b) inulin, which comprises at least about 25 percent by weight of the combination of the sweetening agent and the inulin (e.g., specification, page 3, lines 5-10; page 5, lines 22-27; page 7, lines 3-7; page 9, lines 5-9; page 9, line 21 to page 10, line 14; page 13, lines 4-12; etc.).

6. Independent claim 26 recites a method for preparing a foodstuff that includes: (a) combining a first ingredient with at least one sweetening agent comprising a polyol; and (b) combining a second ingredient, which may be the same as or different than the first ingredient, with inulin in an amount which comprises at least about 25 percent by weight of the combination of the at least one sweetening agent and the inulin (e.g., specification, page 3, lines 5-10 and 17-25; page 5, lines 22-28; page 7, lines 3-7; page 15, line 1 to page 17, line 25; etc.).

7. Independent claim 28 recites a method for preparing a foodstuff that includes adding to the foodstuff (a) at least one sweetening agent comprising a polyol; and (b) inulin, which comprises at least about 25 percent by weight of the combination of the at least one sweetening agent and the inulin; wherein the at least one sweetening agent and the inulin are added to the foodstuff either in combination at the same time, or else in separate portions at different times (e.g., specification, page 3, lines 5-10; page 3, line 26 to page 4, line 2; page 5, lines 22-28; page 7, lines 3-7; page 14, lines 22-28; etc.).

As described in the specification, Appellant has discovered that "the unpleasant side effects of diarrhea associated with consumption of foodstuffs sweetened by sweetening agents such as polyols ... can be reduced or eliminated by incorporating inulin into the sweetening compositions in certain minimum amounts" (e.g., p. 4, ll. 3-8, emphasis added). More specifically, Appellant has discovered that a "minimum amount" of inulin sufficient to reduce diarrhea induced by sweetener consumption corresponds to "at least about 25 percent by weight of the combination of sweetening agent or agents and inulin" (e.g., specification, p. 7, ll. 3-7, emphasis added).

Each of the pending independent claims 1, 13, 20-22, 26, and 28 recites the above-described minimum amount of inulin sufficient to reduce diarrhea induced by consumption of polyol-containing sweeteners.

Grounds of Rejection to be Reviewed on Appeal

The ground of rejection which Appellant wishes the Board to review on Appeal is the rejection of claims 1-29 under 35 U.S.C. § 103 (a) as being obvious in view of *James* (United States Patent No. 5,721,004), *Teeuwen et al.* (abstract), *Thon* (abstract), *Birch et al.* (abstract), and *Laurenzo et al.* (European Patent Application No. EP 0 787 745 A2).

Argument

Appellant respectfully requests reconsideration by the Board of the rejection of claims 1-29 under 35 U.S.C. § 103 (a) as being obvious in view of *James*, *Teeuwen et al.*, *Thon*, *Birch et al.*, and *Laurenzo et al.*

As explained in detail below, three arguments are presented in support of Appellant's request for reversal of the final rejection. Briefly summarized, these arguments are as follows:

1. The appealed claims are directed to sweetening compositions, foodstuffs, and methods for preparing foodstuffs. Each of the appealed independent claims recites inulin in an amount which comprises at least about 25 percent by weight of a combination of sweetening agent and inulin in order to reduce or eliminate diarrhea and related symptoms. The Examiner has not provided any prior art that teaches or

suggests the claimed amounts of inulin or any prior art that even acknowledges or recognizes that diarrhea induced by sweetener consumption can be reduced or eliminated through the use of inulin. In view of the foregoing facts, Appellant respectfully submits that Examiner has not established a *prima facie* case of obviousness.

2. In *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538, 218 USPQ 871, 879 (Fed. Cir. 1983), the Court of Appeals for the Federal Circuit stated that "evidence rising out of the so-called 'secondary considerations' must always when present be considered en route to a determination of obviousness." Appellant has submitted extensive evidence establishing a long-felt but unsolved need for a solution to the problem of diarrhea and related maladies associated with the ingestion of polyol-containing sweeteners. In view of the foregoing facts, Appellant respectfully submits that the submitted evidence establishing a long-felt but unsolved need is more than sufficient to overcome a hypothetical *prima facie* case of obviousness assuming *arguendo* that such a case had been established.

3. The Manual of Patent Examining Procedure (MPEP) 716.01 states that "[w]here the evidence is insufficient to overcome the rejection, the examiner must specifically explain why the evidence is insufficient" and that "[g]eneral statements such as ... 'the evidence is not commensurate with the scope of the claims' without an explanation supporting such findings are insufficient." However, the Examiner has not provided a specific explanation as to why the submitted evidence is perceived as being insufficient to overcome the rejection. In view of the foregoing facts, Appellant respectfully submits that the Examiner's conclusion that the submitted arguments and evidence are not persuasive on the basis that the "[e]vidence provided is not commensurate in scope with the claims," as stated on page 4 of the Final Office Action dated October 7, 2003, is improper.

Argument 1 – The Failure to Establish a *Prima Facie* Case of Obviousness

MPEP 2142 states that "[to] establish a *prima facie* case of obviousness ... the prior art reference ... must teach or suggest all the claim limitations." *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

However, the combination of *James*, *Teeuwen et al.*, *Thon*, *Birch et al.*, and *Laurenzo et al.* fails to teach, either expressly or inherently, each and every element recited in rejected independent claims 1, 13, 20-22, 26, and 28, and provides no teaching or suggestion as to the desirability of modifying the compositions described therein to include each and every element of the rejected independent claims. By analogy, and in view of 35 U.S.C. § 112, fourth paragraph, which states that "[a] claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers," the combination of references also fails to teach, either expressly or inherently, each and every element recited in dependent claims 2-12, 14-19, 23-25, 27, and 29, and provides no teaching or suggestion as to the desirability of modifying the compositions described therein to include each and every element of the rejected dependent claims.

At a minimum, the combination of references fails to teach or suggest the amount of inulin recited in each of the rejected independent claims—namely, an amount at least about 25 percent by weight of the combination of sweetening agent and inulin.

The Examiner argues in the Final Office Action dated October 7, 2003 that the claimed amounts of inulin are "no more than a matter of choice and well-within the skill of the art," and that "[at] most the amounts selected are no more than optimization" (page 3). However, there would have been absolutely no motivation or suggestion to modify the cited references in order to arrive at the claimed amounts of inulin inasmuch as none of the applied references even acknowledges or recognizes that diarrhea induced by sweetener consumption can be reduced or eliminated through the use of inulin. This teaching is limited to Appellant's disclosure and, in accordance with MPEP 2143, cannot provide the basis for a motivation to modify or combine references.

James describes methods for producing fat-free and low-fat viscous dressings using inulin as a fat mimetic. *Teeuwen et al.* describes the use of inulin as a partial replacement for fat and sugar, and refers to the combination of inulin with an intense sweetener. *Thon* describes the use of inulin as a sugar substitute used in combination with a sweetener. *Birch et al.* describes the composition and properties of diabetic jams. *Laurenzo et al.* describes processes for clarifying crude inulin extracts. None of these references makes any reference whatsoever to alleviating symptoms of diarrhea

induced by sweetener consumption. Moreover, none of these references contains any teaching or suggestion that a minimum amount of inulin used in combination with a sweetener is sufficient to reduce or eliminate diarrhea induced by consumption of the sweetener. Furthermore, none of these references contains any teaching or suggestion that an efficacious minimum amount of inulin corresponds to at least about 25 percent by weight of a combination of sweetener and inulin.

For at least these reasons, and in accordance with MPEP 2142, Appellant respectfully submits that a *prima facie* case for the obviousness of rejected claims 1-29 in view of *James*, *Teeuwen et al.*, *Thon*, *Birch et al.*, and *Laurenzo et al.* has not been established. Accordingly, reversal of this rejection is respectfully requested.

Argument 2 – The Secondary Considerations Rebut any Hypothetical *Prima Facie* Case of Obviousness even if Examiner had Established Same

Assuming *arguendo* that a *prima facie* case for the obviousness of rejected claims 1-29 had been established, which Appellant respectfully submits that it has not, the *prima facie* case would be overcome on the basis of secondary considerations and, more particularly, on the basis that the claimed invention provides a solution to a long-felt but unsolved need in the art.

In accordance with MPEP 716.01(a) and MPEP 2141.01, objective evidence or secondary considerations such as long-felt but unsolved needs are relevant to the issue of obviousness and must be considered in every case in which they are present. The Court of Appeals for the Federal Circuit stated in *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538, 218 USPQ 871, 879 (Fed. Cir. 1983) that "evidence rising out of the so-called 'secondary considerations' must always when present be considered en route to a determination of obviousness." Such evidence might give light to circumstances surrounding the origin of the subject matter sought to be patented. As indicia of obviousness or unobviousness, such evidence may have relevancy. *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966); *In re Palmer*, 451 F.2d 1100, 172 USPQ 126 (CCPA 1971); *In re Fielder,* 471 F.2d 640, 176 USPQ 300 (CCPA 1973).

As noted in the specification, polyols (e.g., xylitol, sorbitol, mannitol, maltitol, etc.), as well as other sweetening agents (e.g., monosaccharides, polysaccharides,

etc.), have been used to good advantage as substitutes for sucrose in a variety of foodstuffs. However, the ingestion of higher doses of such sweetening agents and/or the lack of systemic adaptation to such sweetening agents in sensitive individuals may result in unpleasant side effects, which include diarrhea and symptoms associated with diarrhea (e.g., specification, p. 2, ll. 13-21).

As evidence of the long-felt but unsolved need asserted by Appellant, Appellant has previously submitted seven Exhibits with the Responses filed July 24, 2001 and July 14, 2003. These Exhibits are attached herewith and labeled I-VII. A new Exhibit in accordance with 37 CFR § 41.33(d)(1), which further establishes the existence of the long-felt but unsolved need, is submitted herewith as Exhibit VIII.

Exhibit I shows a candy wrapper warning that the presence of the polyol ingredients lactitol and maltitol may produce a laxative effect.

Exhibit II shows a candy wrapper warning that the presence of the polyol ingredients sorbitol or mannitol, or the presence of hydrogenated starch hydrolysate, may produce a laxative effect.

Exhibit III shows candy wrappers from two foodstuffs produced by the same manufacturer, one of which contains a warning against the possibility of a laxative effect, the other of which does not. The foodstuff bearing the warning contains the polyol sucrose replacement maltitol, whereas the foodstuff without a warning contains ordinary sugar (i.e., sucrose).

Exhibit IV shows the label of a sorbitol solution, which identifies this polyol as having dual use as a sweetening agent and as a laxative.

Exhibit V is an abstract of an article entitled "Dose-Related Gastrointestinal Response to the Ingestion of Either Isomalt, Lactitol or Maltitol in Milk Chocolate" by G. A. Koutsou et al. (*Eur. J. Clin. Nutr.* **1996**, *50*, 17-21), which describes that healthy volunteers aged 18-24 years who ingested polyol-containing milk chocolate experienced gastrointestinal responses including flatulence, borborygms, colic, increased motion frequency, and loose stools.

Exhibit VI is an abstract of an article entitled "Sugar Alcohols as Bulk Sweeteners" by W. L. Dills, Jr. (*Annu. Rev. Nutr.* **1989**, *9*, 161-186), which states that "[a]ll of the polyols can cause osmotic diarrhea in humans if higher levels are

consumed," and that "[t]his fact is noted in the labeling of products containing mannitol and sorbitol in the United States."

Exhibit VII is an abstract of an article entitled "Use of Xylitol as Sugar Substitute in Diabetic Children" by H. Forster et al. (*Fortschr. Med.* **1977**, *95*, 99-102), which indicates that a diabetic child given xylitol as a substitute for sugar was unable to continue in the study due to the onset of diarrhea.

Exhibit VIII is the text of a letter dated September 22, 1999 submitted to the Commissioner of the U.S. Food and Drug Administration by the Center for Science in the Public Interest (CSPI). This letter urges the Commissioner to require explicit label notices on products containing sugar alcohols in view of the diarrhea and other gastrointestinal problems that are associated with their ingestion. The letter states that "[i]n clinical trials and in the general public, sugar alcohols have resulted in serious diarrhea and other symptoms." The letter also states the following:

> While CSPI's petition focues primarily on the labeling requirements for products containing sorbitol, the same considerations apply to products containing other sugar alcohols, such as mannitol, maltitol, isomalt, xylitol, and hydrogenated starch hydrolysate. Those substances also may cause diarrhea and other gastrointestinal problems, particularly in children and other susceptible individuals.

It is abundantly clear from a consideration of Exhibits I, II, and III that the manufacturers of the foodstuffs originally packaged in these wrappers were well aware of the serious problems associated with the ingestion of polyols. Furthermore, it is abundantly clear from a consideration of Exhibit IV that a foodstuff manufacturer wishing to employ sorbitol as a sweetening agent would be well aware of the possible undesirable laxative effect that could result from ingestion thereof. Moreover, it is abundantly clear from a consideration of Exhibits V, VI, VII, and VIII that the cause-effect relationship between polyol-consumption and diarrhea and/or related symptoms is very well established and recognized within the art, and poses a significant health risk. Nonetheless, in spite of the widespread recognition of the link between polyol-consumption and gastrointestinal disorders, manufacturers and providers of polyol-containing foodstuffs have been wholly incapable of mitigating or preventing the undesirable effects of polyol consumption beyond providing generic warnings

discouraging excessive consumption, such as those illustrated in Exhibits I, II, III, and IV.

This long felt but unsolved need, evidenced by the Exhibits described above, is successfully addressed by use of the claimed invention, in which inulin is added to sweetening compositions in the claimed amounts (e.g., specification, page 7, lines 3-7). However, none of the cited references, alone or in combination, teaches or suggests inulin in an amount which comprises at least about 25 percent by weight of a combination of sweetening agent or agents and inulin—that is, in an amount sufficient to reduce diarrhea induced by sweetener consumption. Indeed, none of the cited references even acknowledges or recognizes that diarrhea induced by sweetener consumption may be reduced or eliminated through the use of inulin.

Appellant respectfully submits that if the claimed invention would have been obvious in view of the cited references, which Appellant respectfully submits that it would not have been, then manufacturers of polyol-containing foodstuffs would have long ago employed Applicant's invention in order to reduce the undesirable side effects associated with consumption of their products, thus boosting sales, increasing consumer satisfaction, etc. The fact that the claimed invention has not previously been recognized as a viable solution to the long-felt but unsolved need is a testament to the non-obviousness of the claimed invention.

For at least these reasons, and in accordance with MPEP 716.01(a) and 2141.01, Appellant respectfully submits that any *prima facie* case for the obviousness of rejected claims 1-29 in view of *James*, *Teeuwen et al.*, *Thon*, *Birch et al.*, and *Laurenzo et al.* has been overcome on the basis of secondary considerations. Accordingly, reversal of this rejection is respectfully requested.

Argument 3 – The Examiner has Failed to Provide the Required Explanation as to why the Submitted Evidence of Secondary Considerations is Perceived as Insufficient

Appellant notes for the record that the above-described Exhibits I-VIII are merely representative of an abundance of literature evidence establishing the long-felt but unsolved need for a solution to the problem of diarrhea and related maladies associated with the ingestion of polyol sweeteners. Although these Exhibits have been presented

in the course of prosecution, Appellant respectfully submits that the Examiner has not provided any explanation as to why this evidence is perceived as insufficient. On page 4 of the Final Office Action dated October 7, 2003, the Examiner states that "Applicant's arguments with respect to long felt need are not persuasive for the following reasons" and proceeds to state that the "[e]vidence provided is not commensurate in scope with the claims." However, MPEP 716.01 explicitly states:

> Where the evidence is insufficient to overcome the rejection, the examiner must specifically explain why the evidence is insufficient. General statements such as ... "the evidence is not commensurate with the scope of the claims" without an explanation supporting such findings are insufficient.

The Examiner further states that the "[e]vidence is directed to reduction of diarrhea induced by a sweetener consumption yet the claims are not directed to anti-diarrhea composition [*sic*]". As noted above, the specification clearly establishes that the sweetening compositions of the claimed invention, as well as foodstuffs containing these sweetening compositions and methods for preparing such foodstuffs, provide anti-diarrheal benefits (e.g., page 4, lines 3-15; page 7, lines 3-7; page 8, line 23 to page 9, line 4). Appellant respectfully submits that the intended use of the claimed invention is not relevant to the probative value of the Exhibits establishing a long-felt but unsolved need or to the question of whether the claimed minimum amount of inulin would have been obvious to one of ordinary skill in the art. The claimed minimum amount of inulin represents a hitherto unrecognized solution to a long felt but unsolved need for preventing or minimizing diarrhea and/or related symptoms induced by the consumption of polyols. This minimum amount is not arbitrary nor is it a matter of mere optimization, as was suggested in the Final Office Action (e.g., page 3). Moreover, no combination of the applied references teaches or suggests this claimed minimum amount.

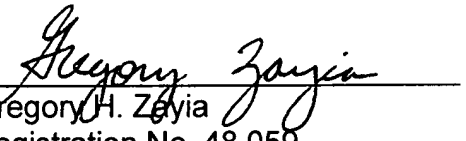
For at least these reasons, and in accordance with MPEP 716.01(a) and 2141.01, Appellant respectfully submits that any *prima facie* case for the obviousness of rejected claims 1-29 in view of *James*, *Teeuwen et al.*, *Thon*, *Birch et al.*, and *Laurenzo et al.* has been overcome on the basis of secondary considerations. Accordingly, reversal of this rejection is respectfully requested.

Conclusion

In conclusion, Appellant respectfully submits that the Examiner has failed to establish a *prima facie* case for the obviousness of rejected claims 1-29. Furthermore, the Examiner has failed to address the secondary considerations of a long-felt but unsolved need, which would overcome any such *prima facie* case of obviousness.

For at least the reasons set forth above, Appellant respectfully submits that the invention defined in appealed claims 1-29 is neither anticipated by nor would have been obvious in view of *James*, *Teeuwen et al.*, *Thon*, *Birch et al.*, and *Laurenzo et al.* Accordingly, reversal of all grounds of rejection is respectfully requested.

Respectfully submitted,



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Claims Appendix

1. A sweetening composition comprising:

at least one sweetening agent comprising a polyol; and

inulin, which comprises at least about 25 percent by weight of the combination of said at least one sweetening agent and said inulin.

2. The composition of claim 1, wherein said polyol is selected from the group consisting of xylitol, sorbitol, maltitol, mannitol, isomalt, isomaltitol, lactitol, hydrogenated starch hydrolysates, glycerol, propylene glycol, erythoritol, galactitol, and combinations thereof.

3. The composition of claim 1, wherein said polyol is selected from the group consisting of xylitol, sorbitol, maltitol, mannitol, and combinations thereof.

4. The composition of claim 1, wherein said polyol is selected from the group consisting of xylitol, sorbitol, and a combination thereof.

5. The composition of claim 1, wherein said polyol is xylitol.

6. The composition of claim 1, in which said sweetening agent further comprises a polysaccharide containing at least three monosaccharide units.

7. The composition of claim 1, wherein said sweetening agent further comprises a monosaccharide selected from the group consisting of glyceraldehyde, erythrose, threose, ribose, arabinose, xylose, lyxose, allose, altrose, glucose, mannose, gulose, idose, galactose, talose, dihydroxyacetone, erythrulose, ribulose, xylulose, psicose, fructose, sorbose, tagatose, and combinations thereof.

8. The composition of claim 7, wherein said monosaccharide is selected from the group consisting of fructose, glucose, and a combination thereof.

9. The composition of claim 7, wherein said monosaccharide comprises fructose.

10. The composition of claim 1, wherein said sweetening agent further comprises a disaccharide selected from the group consisting of maltose, lactose, sucrose, isomaltulose, maltulose, isomaltose, cellobiose, and combinations thereof.

11. The composition of claim 10, wherein said disaccharide comprises maltose.

12. The composition of claim 10, wherein said disaccharide comprises lactose.

13. A sweetening composition comprising:

a sweetening agent comprising a polyol and fructose; and

inulin, which comprises at least about 25 percent by weight of the combination of said sweetening agent and said inulin.

14. The composition of claim 13, wherein said polyol comprises xylitol.

15. The composition of any one of claims 1 to 14, wherein said inulin comprises at least about 30 percent by weight of the combination of said at least one sweetening agent and said inulin.

16. The composition of any one of claims 1 to 14, wherein said inulin comprises at least about 35 percent by weight of the combination of said at least one sweetening agent and said inulin.

17. The composition of any one of claims 1 to 14, wherein said inulin comprises at least about 40 percent by weight of the combination of said at least one sweetening agent and said inulin.

18. The composition of any one of claims 1 to 14, wherein said inulin comprises polysaccharides having molecular weights up to and including about 2288, in an amount of at least 75 percent by weight of said inulin.

19. The composition of any one of claims 1 to 14, wherein said inulin comprises polysaccharides having molecular weights above about 2288, in an amount of at least 75 percent by weight of said inulin.

20. A sweetening composition comprising:

a sweetening agent comprising at least one polyol selected from the group consisting of xylitol, sorbitol, and a combination thereof; and

inulin, which comprises at least about 25 percent by weight of the combination of said at least one sweetening agent and said inulin.

21. A sweetening composition comprising:

a sweetening agent comprising xylitol, lactose, and fructose; and

inulin, which comprises at least about 25 percent by weight of the combination of said sweetening agent and said inulin.

22. A sweetening composition comprising:

a sweetening agent comprising lactose and xylitol; and

inulin, which comprises at least about 25 percent by weight of the combination of said sweetening agent and said inulin..

23. A foodstuff comprising a sweetening composition as recited in any one of claims 1, 13, 14, 20, 21 or 22.

24. A foodstuff comprising a sweetening composition as recited in any one of claims 1, 13, 14, 20, 21 or 22, wherein said foodstuff is selected from the group

consisting of gum, candy, ice cream, cheese, yogurt, cottage cheese, cake, cookies and beverages.

25. The composition of any one of claims 1, 13, 14, 20, 21, 22 or 23, wherein said sweetening agent further comprises at least one intense sweetener.

26. A method for preparing a foodstuff comprised of a plurality of ingredients, said method comprising:

(a) combining a first of said ingredients with at least one sweetening agent comprising a polyol; and

(b) combining a second of said ingredients with inulin in an amount which comprises at least about 25 percent by weight of the combination of said at least one sweetening agent and said inulin; wherein

said first and said second of said ingredients are either the same ingredient or else different ingredients.

27. The method of claim 26, wherein said foodstuff is selected from the group consisting of candy, ice cream, cake, cookies and beverages.

28. A method for preparing a foodstuff, said method comprising:

adding to said foodstuff:

(i) at least one sweetening agent comprising a polyol; and

(ii) inulin, which comprises at least about 25 percent by weight of the combination of said at least one sweetening agent and said inulin; wherein

said at least one sweetening agent and said inulin are added to said foodstuff either in combination at the same time, or else in separate portions at different times.

29. The method of claim 28, wherein said foodstuff is selected from the group consisting of candy, ice cream, cheese, cottage cheese, milk, cake, cookies and beverages.

Evidence Appendix

Exhibits I-VIII are attached below.

Exhibits I-VII were previously submitted with the Responses filed July 24, 2001 and July 14, 2003 and were previously entered into the record by the Examiner.

Although Exhibit VIII was not presented prior to the filing of the Notice of Appeal, Appellant respectfully submits that this exhibit complies with 37 CFR § 41.33(d)(1) and, therefore, respectfully requests that it be admitted into the record at the present time. Exhibit VIII establishes clear evidence that clinical researchers recognize polyol-consumption as being causally linked to diarrhea and/or related symptoms, and that they regard the ingestion of polyols as posing a sufficiently serious health risk to merit explicit label notices by the U.S. Food and Drug Administration. Appellant respectfully submits that Exhibit VIII provides clear evidence of the long felt but unsolved need and, as such, overcomes the obviousness rejection under appeal on the basis of secondary considerations.

EXHIBIT I

The Fannie May Legacy

Quality isn't just a word at Fannie May, it's a way of life...and has been for over 75 years. By using only the freshest ingredients, Fannie May continues to make the finest candies available... as good as the day H. Teller Archibald opened his first Fannie May Shop in 1920 in Chicago, Illinois.

Our commitment to freshness continues and you will taste the difference. We guarantee it.

Enjoy the quality of Fannie May Candies with these sugar free fruit-flavored pops in an assortment of grape, lemon, lime, orange, cherry, and pineapple. Fannie May Candies...quite simply the finest candies available.

Sugar free candies are made for those who prefer less sugar or are on a sugar-restricted diet. Although this is not a reduced calorie product, it will not promote tooth decay. This product may produce a laxative effect after excessive consumption. People on a restricted diet should consult their physician before consuming.

Ingredients: Lactitol, Maltitol Syrup, Aspartame, Citric Acid, Natural and Artificial Flavor, Yellow #5, Yellow #6, Red #40, Red #3, Blue #1

Phenylketonurics: Contains Phenylalanine

Manufactured by Fannie May Candies, a division of Archibald Candy Corporation Chicago, IL 60607

Nutrition Facts

Serving Size 1 piece (10.5 g)
Servings per Container 12

Amount Per Serving

Calories 42 Calories from Fat 0

	% Daily Value*
Total Fat 0g	0%
Saturated Fat 0g	0%
Cholesterol 0mg	0%
Sodium 0mg	0%
Total Carbohydrates 10g	3%
Dietary Fiber 0g	
Sugars 0g	
Protein 0g	

Vitamin A 0% • Vitamin C 0%

Calcium 0% • Iron 0%

*Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs.

	Calories	2000	2500
Total Fat	Less than	65g	80g
Sat. Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2400mg	2400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

Calories per gram

Fat 9 Carbohydrates 4 Protein 4

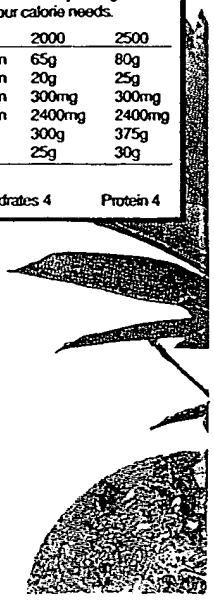

EXHIBIT II

"One Taste... Our Best Advertisement!"®

EDA Candies are manufactured with sorbitol, a cool refreshing sugar substitute which occurs naturally in many fruits and berries. Sorbitol has been thoroughly tested and widely used for over 100 years. EDA candies are made without artificial sweeteners and contain no saccharin, acesulfame potassium or aspartame.

Dry Mouth?, Get your juices flowing with delicious EDA candies!
"Melts in your mouth not in the wrapper!"

Nutrition Facts

Serving Size 5 pieces (15g)
Servings Per Container about 11

Amount Per Serving	
Calories 60	
	% Daily Value*
Total Fat 0g	0%
Cholesterol 0mg	0%
Sodium 0mg	0%
Total Carbohydrate 15g	5%
Sugars 0g	
Sorbitol 15g	
Protein 0g	

Not a significant source of Calories from Total Fat, Saturated fat, Dietary Fiber, Vitamin A, Vitamin C, Calcium, and Iron.

*Percent Daily Values are Based on a 2,000 calorie diet.

Available in 21 mouth water flavors....

MIXED FRUITS	TROPICAL MIX	OLD-TYME MIX
Cherry	Banana	Butterscotch
Green Apple	Butter Rum	Chocolate
Lemon	Coconut	Cinnamon
Lemon-Lime	Lemon-Lime	Icy Peppermint
Orange	Orange	Licorice
Raspberry	Pina Colada	Real Coffee
Strawberry	Pineapple	Root Beer
Watermelon	Watermelon	Spearmint

Ingredients:
Sorbitol, gum arabic, citric acid, natural and artificial flavors, colors added. (FD&C Red # 40, Blue #1, Blue #2, Turmeric)

EXCHANGE INFO: 1 serving=1fruit exchange. These exchanges are useful for people with diabetes and those in weight loss programs.

DIABETICS: This product may be useful in your diet on the advice of a physician. This is not a reduced calorie food.

As in all candies made with sorbitol, mannitol, or hydrogenated starch hydrolysate, EXCESSIVE CONSUMPTION MAY HAVE A LAXATIVE EFFECT IN SENSITIVE PERSONS. According to the FDA, 50 grams (17 candies- about 3 servings) is well tolerated by most individuals. Since sensitivity varies among individuals, we recommend starting with one or two candies and gradually increasing as desired. A tolerance can be developed in much the same way as with fiber.

Questions or comments about this product?
Call toll-free weekdays: (9-3 EST) 1-800-438-3327

Manufactured by
LEHMAN SUGAR FREE CONFECTIONS, INC.
BROOKLYN, NY 11203 (800-GET-EDAS)

EXHIBIT III

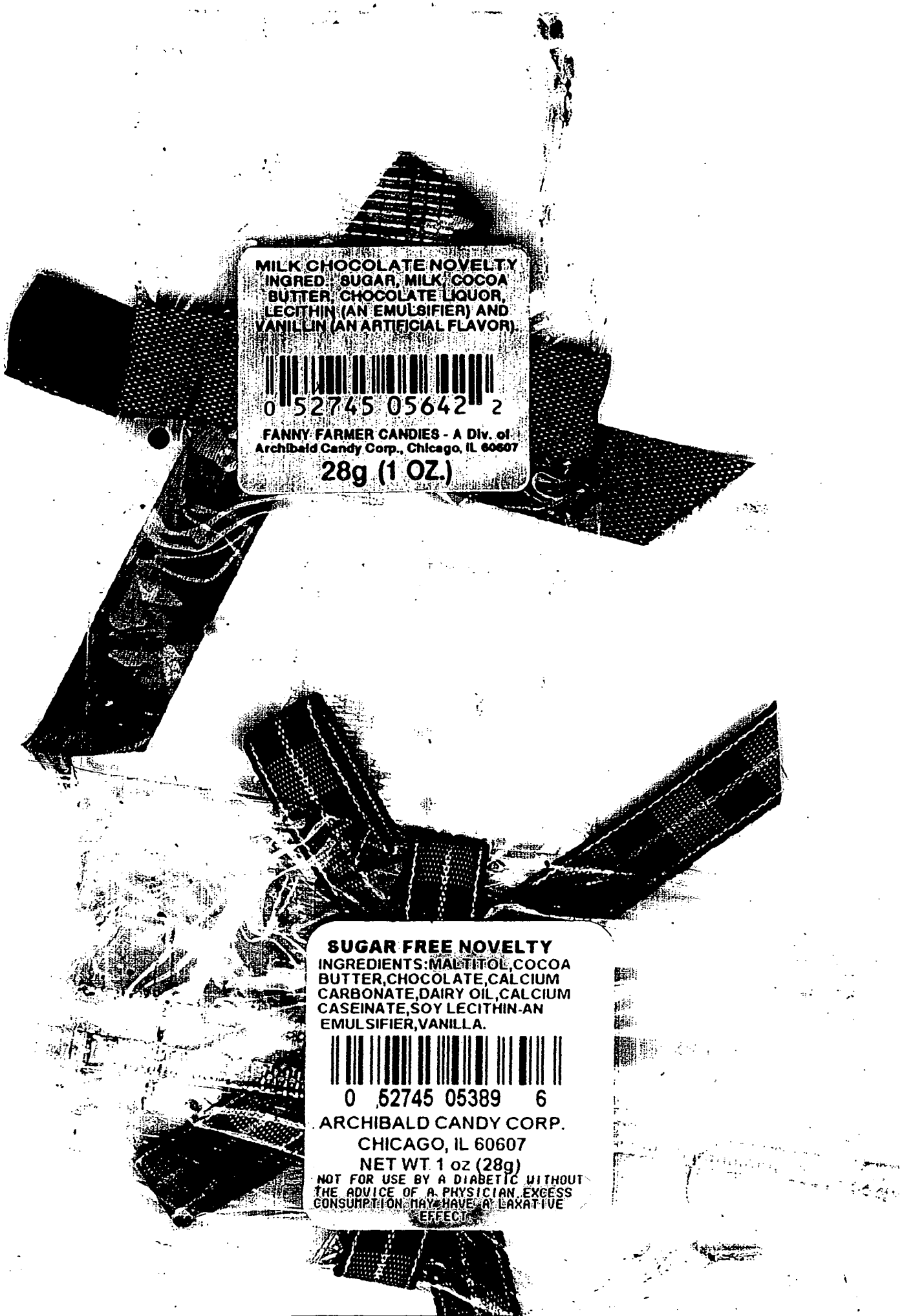
MILK CHOCOLATE NOVELTY
INGRED.: SUGAR, MILK, COCOA BUTTER, CHOCOLATE LIQUOR, LECITHIN (AN EMULSIFIER) AND VANILLIN (AN ARTIFICIAL FLAVOR).
0 52745 05642 2
FANNY FARMER CANDIES - A Div. of Archibald Candy Corp., Chicago, IL 60607
28g (1 OZ.)
SUGAR FREE NOVELTY
INGREDIENTS:MALTITOL,COCOA BUTTER,CHOCOLATE,CALCIUM CARBONATE,DAIRY OIL,CALCIUM CASEINATE,SOY LECITHIN-AN EMULSIFIER,VANILLA.
0 52745 05389 6
ARCHIBALD CANDY CORP.
CHICAGO, IL 60607
NET WT 1 oz (28g)
NOT FOR USE BY A DIABETIC WITHOUT THE ADVICE OF A PHYSICIAN.EXCESS CONSUMPTION MAY HAVE A LAXATIVE EFFECT.

EXHIBIT IV

Dist. By Marlex Pharmaceuticals,Inc.,
New Castle, DE 19720. Made in USA.

LOT 1497

EXP 9 2004

MARLEX PHARMACEUTICALS

NDC 10135-137-08

USP

SORBITOL SOLUTION U.S.P. - 70%

For use as a laxative, Pharmaceutical vehicle and sweetening agent.

One Pint (473 mL)

DO NOT USE IF IMPRINTED NECK/CAP SEAL IS BROKEN OR MISSING.

INDICATIONS: For use as a laxative, pharmaceutical vehicle and a sweetening agent.

DIRECTIONS: ORAL: Adults and children 12 years of age and older: 2 to 3 tablespoons per day (equivalent to approximately 27 to 40 grams of sorbitol) in a single daily dose or as directed by a physician. **Children under 12 years of age:** consult a physician. **RECTAL: Adults and children 12 years of age and older:** Rectal enema dosage is 120 mL of a 25 to 30 percent weight/volume solution in a single daily dose or as directed by a physician. **Children under 12 years of age:** consult a physician.

NOTE: A 25 to 30 percent weight to volume sorbitol solution can be obtained by diluting 1 part of this product with 2.3 parts water.

INGREDIENTS: Sorbitol 70% U.S.P., purified water 30%.

WARNING: KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN. In case of accidental overdose, seek professional assistance or contact your doctor or a poison control center immediately. Do not use laxative products for a period longer than one week or when abdominal pain, nausea or vomiting are present unless directed by a physician. If you have noticed a sudden change in bowel habits that persists over a period of 2 weeks, consult a physician before using a laxative. Rectal bleeding or failure to have a bowel movement after use of a laxative may indicate a serious condition. Discontinue use and consult your physician.

AS WITH ANY DRUG: If you are pregnant or nursing a baby, seek the advice of a doctor before using this product.

Do not freeze. Store at controlled room temperature 15-30°C (59-86°F). Below this temperature the Sorbitol Solution thickens and cloudiness may occur. The application of heat may restore the fluidity and clarity without affecting the quality of the Sorbitol.

Store in original container and keep away from children.

Keep container tightly closed after each use. Use by expiration date on package.

Rev 3 5/01

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EXHIBIT V

Eur J Clin Nutr. 1996 Jan;50(1):17-21. Related Articles, Links

Dose-related gastrointestinal response to the ingestion of either isomalt, lactitol or maltitol in milk chocolate.

Koutsou GA, Storey DM, Lee A, Zumbe A, Flourie B, leBot Y, Olivier P.

Nutritional Biosciences Unit, University of Salford, UK.

OBJECTIVES: To determine whether there were differences between different polyols (sugar alcohols) in terms of their ability to stimulate intolerance symptoms when consumed in milk chocolate. Also to discover whether symptomatology can be related to the dose of polyol ingested. DESIGN: The study was of a randomised double-blind cross-over design. SUBJECTS: 59 healthy volunteers aged 18-24 years were recruited from the student population of the University of Salford. All subjects successfully completed the trial. INTERVENTIONS: Subjects ingested 100 g milk chocolate containing 40 g bulk sweetner as either sucrose, isomalt, lactitol or maltitol or a mixture (10:30 w/w) of sucrose and isomalt, sucrose and lactitol or sucrose and maltitol. Each bar was taken as breakfast on one day with following products consumed at 1-week intervals. Subjects reported the incidence and severity of the symptoms of flatulence, borborygms, colic, motion frequency and loose stools. RESULTS: The ingestion of 30 g or 40 g lactitol resulted in a significant increase in the incidence and severity of all symptoms examined compared to reactions after the consumption of standard sucrose-containing chocolate ($P < 0.01$). Similarly, 40 g isomalt led to an increased incidence of all symptoms, including mild laxation ($P < 0.01$), but unlike lactitol none was rated as being severe. A reduction in isomalt to 30 g was marked by increased tolerance with evidence of only mild borborygms ($P < 0.01$), mild flatulence, colic, and laxation ($P < 0.05$), with no increase in motion frequency ($P < 0.35$). Ingestion of 40 g maltitol caused less intolerance than 40 g isomalt, with evidence of only flatulence, borborygms and colic ($P < 0.01$), symptoms being rated as only mild. A reduction to 30 g led to a decrease in all symptoms except mild flatulence. Maltitol did not have any laxative effect when ingested at either 30 g ($P = 0.32$) or 40 g ($P = 0.13$) per day. CONCLUSIONS: This work has shown that there are significant differences in the reporting of gastrointestinal symptomatology following the consumption of isomalt, lactitol and maltitol incorporated into milk chocolate. However, with all three polyols the incidence and severity of symptomatology was dose dependent.

Publication Types:

- Clinical Trial
- Randomized Controlled Trial

PMID: 8617186 [PubMed - indexed for MEDLINE]

EXHIBIT VI

Annu Rev Nutr. 1989;9:161-86.

Sugar alcohols as bulk sweeteners.

Dills WL Jr.

Department of Chemistry, Southeastern Massachusetts University, North Dartmouth 02747.

The polyols are a family of bulk sweeteners, some of which are currently used in the United States and in other nations. The use of these compounds is likely to increase in the future. The greatest advantage of polyols as sweeteners is their reduced cariogenicity compared with sucrose, fructose, or glucose. This reduced cariogenicity has been observed with all of the polyols considered in this review. Furthermore, evidence suggests that one of these polyols, xylitol, may have cariostatic properties. More research is needed to clarify the mechanism of this cariostatic effect. Evidence suggests that moderate usage of the polyols in human diets over long periods is not likely to produce many toxic effects. This conclusion is supported by the facts that (a) both sorbitol and mannitol have been used as sweeteners for some time without apparent side effects, and (b) extensive long-term studies with dietary xylitol in Europe have not yielded any reports of toxicity. At this point there is no reason to believe that the disaccharide polyols differ significantly in a qualitative sense from sorbitol or mannitol with regard to their effects in humans. There are some research needs with regard to the inclusion of the polyol sweeteners in human diets: 1. All of the polyols can cause osmotic diarrhea in humans if higher levels are consumed. This fact is noted in the labelling of products containing mannitol and sorbitol in the United States (see "Current Regulatory Status"). If the disaccharide polyols are to be used as bulk sweeteners, further studies of the dose levels that can cause diarrhea may be needed. 2. The polyols, like other slowly absorbed carbohydrates, enhance the absorption of certain minerals, particularly divalent cations. More comparative and mechanistic studies of this effect are needed. 3. All of the polyols, lactose, and other slowly absorbed carbohydrates appear to cause adrenal medullary hyperplasia at high doses in laboratory rats. Evidence suggests that these lesions are linked in some way to the lactose or polyol-induced changes in calcium homeostasis. Despite long-term use of lactose, sorbitol, and mannitol in human diets, similar lesions in humans have not been reported and some investigators have concluded that the lesion in rats has no relevance to humans. Nevertheless further studies are needed to elucidate the mechanisms of the dietary lactose and polyol-induced adrenal hyperplasias in rats to ascertain definitively if they also operate in other species.(ABSTRACT TRUNCATED AT 400 WORDS)

Publication Types:

- Review
- Review Literature

PMID: 2669868 [PubMed - indexed for MEDLINE]

EXHIBIT VII

Fortschr Med. 1977 Jan 13;95(2):99-102.

Related Articles, Links

[Use of xylitol as sugar substitute in diabetic children]

[Article in German]

Forster H, Boecker S, Walther A.

In 24 diabetic children treated with insulin xylitol was used as a sugar substitute for four weeks in an amount of 30 gms/day. In one case only the xylitol application was terminated before the end of the dietetic period because of diarrhoea. The other children tolerated xylitol fairly well, three of the children found the polyol too sweet. Because of incomplete data, the values of only 18 children were compiled. A significant increase of serum uric acid concentration measuring 1 mg/100 ml was the main side effect of xylitol usage. This effect was favoured by the fact that diabetic children do not use sucrose. As was shown earlier, a sucrose free period is the precondition for the possibility to find a xylitol induced hyperuricemia. In metabolically healthy children the existence of a sucrose induced hyperuricemia is also to be expected, this xylitol effect is, therefore, obviously without pathophysiological significance. Xylitol is suited for use as a sugar substitute in diabetic diet and in caries prophylaxis if the limited dose is observed.

PMID: 832837 [PubMed - indexed for MEDLINE]

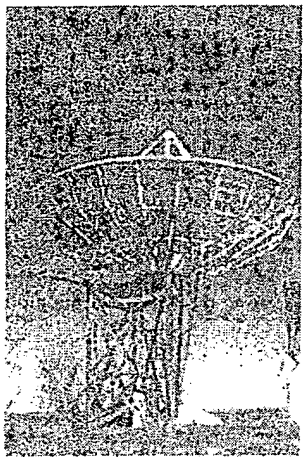
EXHIBIT VIII

CSPI NEWSROOM

CENTER FOR SCIENCE IN THE PUBLIC INTEREST

Letter to the Honorable Jane Henney, M.D., Commissioner

For more information:
202/332-9110



September 22, 1999

The Honorable Jane Henney, M.D., Commissioner
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Commissioner Henney:

The undersigned support the petition filed by the Center for Science in the Public Interest (CSPI) asking the Food and Drug Administration to require that explicit label notices be included on products containing one gram or more of sorbitol per serving.

Having studied the adverse effects of sorbitol on the gastrointestinal systems of both adults and children, we are especially concerned about the lack of public awareness surrounding the numerous "sugar-free" foods, gums, and other products that contain sorbitol and related sugar alcohols. In clinical trials and in the general public, sugar alcohols have resulted in serious diarrhea and other symptoms. While the FDA has required labeling of a small subset of sorbitol-containing products since 1973, we believe the regulation is not stringent enough to protect the public's health. The current regulation falls short in a number of ways:

1. The current regulation does not take into account subsequent clinical studies that demonstrate the ill effects of sorbitol. Under current regulations, only foods likely to provide 50 grams or more of sorbitol per day are required to bear a notice label. That threshold is far too high. Clinical studies performed by us and other researchers have shown that adults may experience diarrhea and other gastrointestinal problems after consuming as little as 10 grams of sorbitol per day. The current regulation must be revised to take those new clinical findings into account. Furthermore, since sorbitol is present in many food products and medicines today, daily consumption might regularly exceed 10 grams per day, including sorbitol from a variety of sources rather than from a single product. The current regulation does not incorporate that consideration.

2. The current labeling notice is too vague, and does not address children's particular susceptibility to sorbitol. The current labeling notice required by the FDA warns that "excess

consumption [of the product] may have a laxative effect." That statement trivializes the potential for extreme gastrointestinal distress, does not clearly indicate what constitutes "excess consumption," and does not point out that children may be affected by relatively small amounts of sorbitol. The notice label should read, as CSPI suggests, "NOTICE: This product contains sorbitol, which may cause diarrhea, bloating, and abdominal pain. Not suitable for consumption by children. To protect yourself, start by eating no more than one serving at a time."

While CSPI's petition focuses primarily on the labeling requirements for products containing sorbitol, the same considerations apply to products containing other sugar alcohols, such as mannitol, maltitol, isomalt, xylitol, and hydrogenated starch hydrolysate. Those substances also may cause diarrhea and other gastrointestinal problems, particularly in children and other susceptible individuals.

Better labeling of sugar alcohols is particularly important considering that FDA regulations allow labels to declare the health benefits (lack of cariogenicity) of foods containing those substances, and to emphasize that the products are "sugar free" and often "low calorie." FDA should take action to ensure that consumers also are fully informed about the adverse effects associated with the sugar alcohols.

Thank you for your prompt attention to this public health matter. (Please respond to the cosigners by writing to the Center for Science in the Public Interest).

Sincerely,

Ray Breitenbach, MD, MS
United States Air Force
Retired Lieutenant Colonel
Flight
Surgeon; Family Physician,
Waterford, MI.

Jeffrey S. Hyams, MD
Head, Division of Digestive
Diseases and Nutrition,
Connecticut Children's Medical
Center; Professor of Pediatrics,
Connecticut University Medical
School, Hartford, CT.

Margaret Lowen Payne, MS, RD
Dietitian Services, Inc., Goshen,
IN.